c.) **Remarks**

Applicant has canceled claims 1-9, 18-20 and 24-68, amended claims 10 and 23, and added new claims 69-94. Support for these amendments and new claims, if necessary, can be found throughout the Specification and also in the original claims. No new matter or new issues are introduced with these amendments and new claims. Thus, claims 10-17, 21-23, and 69-94 are presently pending.

With respect to all amendments and canceled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and moreover has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Remarks Regarding Election/Restrictions

Claims 1-9, 18-20, and 24-68 were withdrawn by the Office Action over the Applicant's traversal. Thus, Group II (claims 10-17 and 21-23) have been elected. Although Applicant proceeds under this election, Applicant continues to maintain all arguments previously described against the restriction requirement.

Remarks Regarding Drawings

The drawings, Figures 7C-E, 8A-C and 9B, were objected to under 37 C.F.R. 1.84(p)(5) as containing reference symbols which are not defined and are not included in the Specification. According to 37 C.F.R. 1.85(p)(5):

> "Reference characters not mentioned in the description shall not appear in the drawings. Reference characters mentioned in the description must appear in the drawings."

Applicant respectfully traverses this objection. All of the reference characters in the drawings indicated 7C-E, 8A-C and 9B are fully described in the Specification. Regarding figure 7C-E, the Examiner is directed to pages 25, line 9, through page 26, line 2. Regarding figure 8A-

C, the Examiner is directed to page 26, lines 8-22. Regarding figure 9B, the Examiner is directed to pages 26, line 27, through page 27, line 14.

Remarks Regarding Improper Dependent Form

Claim 23 was objected to under 37 C.F.R. 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant has amended this claim in order to facilitate prosecution, and without admitting any improper dependence. Claim 23 is now an independent claim and therefore does not depend from any other independent claim. Thus, the improper dependence objection is moot, and Applicant respectfully requests withdrawal of this objection.

Remarks Regarding 35 U.S.C. §112

Claims 10-17 and 21-23 stand rejected under 35 U.S.C. 112, first paragraph, under the enablement and written description requirements. Applicant respectfully traverses these rejections.

A. Enablement

According to the Office Action:

> "...[T]he Specification, while being enabling for *the recombinant human pleiotrophin receptor protein ALK comprising one or more but not all regions selected from the group consisting of an extracellular domain (ECD), an intracellular domain (ICD), a pleiotrophin binding site, a transmembrane domain, and combinations thereof as well as compositions therof,* does not reasonably provide enablement for *other variants, fragments, domains, or petido-mimetics as well as compositions thereof.*"

Applicant respectfully traverses this rejection. Paragraphs 8 to 16 of the Office action object to all of claims 10-17 and 21-23 as being not enabled because the "the claims are drawn very broadly to *any* pleiotrophin receptor protein lacking a region or domain. The language of the claims encompasses *all species* of pleiotrophin receptor as well as unknown or as of yet identified pleiotrophin receptors" [Office Action ¶9, emphasis added]. However, claim 10, as amended, does not claim *all species* of pleiotrophin, but claims a *human pleiotrophin receptor polypeptide*, as described in the Specification. Since claims 11-17, 21 and 22 depend from claim

10, these claims are also directed to recombinant *human pleiotrophin receptor* polypeptides. Similarly, independent claim 23 claims a composition comprising a peptido-mimetic of the *pleiotrophin binding site of human ALK*. Thus, this objection is now moot. Claims 10-17 and 21-23 are drawn to the human pleiotrophin receptor described in the Specification.

Paragraph 12 of the Office Action further objects that "predicting the identity and function of domains of *any given pleiotrophin* receptor protein based solely on a single species of pleiotrophin receptor as highly problematic" [Office action ¶12, emphasis added]. Applicant reiterates that the claims are drawn to the *human pleiotrophin receptor* and thus do not require a prediction of identity and function of domains of *any given pleiotrophin*.

Paragraph 15 of the Office Action objects that "predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex." Applicant respectfully submits that this objection is irrelevant, given that claims 10-17 and 21-23 are drawn to recombinant human pleiotrophin receptor ALK polypeptide comprising one or more, but not all regions of a full-length pleiotrophin receptor protein. Thus, these claims do not require a predication of protein structure to ascertain function of the protein.

Thus, the rejection of claims 10-17 and 21-23 for lack of enablement under 35 U.S.C. § 112, first paragraph, is moot or overcome, and Applicant respectfully requests that it be withdrawn.

B. Written Description

Claims 10-17 and 21-23 are further objected to under 35 U.S.C. §112, first paragraph, as allegedly failing the written description requirement for failing to describe "any particular conserved structure, or other distinguishing feature." Paragraphs 17-25 of the Office Action object to claims 10-17 and 21-23 as containing "subject matter not described in the Specification as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention" [Office Action, ¶17].

Applicant respectfully disagrees. Paragraph 18 of the Office Action objects that:

> "The claims require, 'a growth factor binding site, a mitogenic factor biding site, an antigenic domain, tyrosine kinase, a heparin binding site, a glycosylated domain, a non-glycosylated domain, a signaling domain, a functional domain, and a conserved domain' but do not require that the domains posses any particular conserved structure, or other distinguishing feature nor does the Specification delineate their position (via residues numbers) in any given pleiotrophin receptor protein. Thus, the claims are drawn to a genus of domains that are defined by hypothesized function an unknown location."

Applicant first points out that it is unclear which claims the Office Action is objecting to. Specifically, independent claims 10 and 23 do not require identification of any of these objected-to domains. Instead, claim 10 is directed to a recombinant polypeptide comprising one or more, but not all regions of a full-length human pleiotrophin receptor protein. Likewise, independent claim 23 is directed to a composition comprising a peptido-mimetic of the pleiotrophin binding site of human ALK. Dependent claims 20 and 21 are directed to compositions comprising the polypeptide of claim 10, and also do not require any of these objected-to domains. Thus, this objection is moot with respect to independent claims 1 and 10, and dependent claims 20 and 21.

Second, Applicant disagrees with the assertions of this objection. The claims refer specifically to the human pleiotrophin receptor, a structure of which is described in the Specification. Further, the Specification also describes these domains and points out that they are contained within human ALK. See, for example, figure 1(a) and page 9, line 23 to page 10, line 18. (describing human ALK, its homology to other proteins and protein domains in a diverse family of transmembrane proteins (Proite Database PDOC 00604), and the functional domains present on human ALK). Thus, the Specification, including all of the references entirely incorporated therein, describe the structure of a growth factor binding site, a mitogenic factor biding site, an antigenic domain, tyrosine kinase, a heparin binding site, a glycosylated domain, a non-glycosylated domain, a signaling domain, a functional domain, and a conserved domain. In addition to identifying the ALK protein containing these domains, the Specification describes their functional characteristics. As described in the MPEP §2163(3), this level of detail is adequate to fulfill the written description requirement of §112, first paragraph, by showing that the inventor was in possession of the claimed invention at the time it was filed.

Paragraph 20 of the Office Action further objects that "the claims require antigenicity, anti-angiogenic activity, pro-apototic activity, anti-mitotic activity, and anti-cell proliferative activity but do not disclose or require any sent structure to possess these biological activates." Applicant first points out that this objection is moot with respect to claims 10, 11 and 21-23 because these claims do not require antigenicity, anti-angiogenic activity, pro-apototic activity, anti-mitotic activity, and anti-cell proliferative activity.

Applicant further disagrees with this objection because the claims are *not* drawn to a genus of domains that are defined by hypothesized function and unknown location. As described above, the Specification identifies these functions for human ALK, as claimed in all of claims 10-17 and 21-23. The Specification (including all of the references entirely incorporated therein) also described antigenicity, anti-angiogenic activity, pro-apototic activity, anti-mitotic activity, and anti-cell proliferative activity for human ALK. Thus, the claims are not drawn to a genus of domains that are defined by "hypothesized" function, and this objection is overcome.

Paragraph 20 of the Office Action objects that the claims are also drawn to a "genus of domains that are defined by hypothesized function and unknown location," because they claim "peptido-mimetics" which "do not require that the peptido-mimetic posses any particular conserved structure, or other distinguishing feature nor does the Specification delineate a peptido-mimetic of any given pleiotrophin receptor protein." Applicant first points out that this objection is moot with respect to claims 10-17, 21 and 22, because they are not drawn to peptido-mimetics.

Second, applicant disagrees with this objection. Specifically, independent claim 23 is directed at composition comprising a peptido-mimetic of the pleiotrophin binding site of human ALK. The Specification describes human ALK and also characterizes the functional behavior of the pleiotrophin binding site of human ALK. For example, see Figures 1-9 and Examples 1-10 on pages 17-26 of the Specification. Thus, claim 23 is not drawn to a genus of domains defined by hypothesized function and unknown location.

Paragraph 23 of the Office Action further objects that:

> "[A] sequence described only by a function characteristic without any known or disclosed correlation between that function and the structure of the sequence, is

> not a sufficient identifying characteristic to satisfy the written description requirement. The instant claims present such an instance where Applicant has only described what is desired but does not evidence material possession of the invention at the time of filing though means of sequence disclosure or detailing of structure."

Applicant disagrees, and reiterates the arguments made previously; claims 10-17 and 21-23 claim polypeptides based on human ALK as described in the Specification. Further, the Specification describes the sequence for human ALK, functional and structural characteristics of human ALK and domains of human ALK, and correlation between functional and structural characteristics. See, for example, figure 1(a) and page 9, line 23 to page 10, line 18. Thus, applicant has met the written description requirement as defined by MPEP §2163.

In paragraph 24 of the Office Action the Examiner cites the *University of Rochester v. G.D. Searle & Co.,* 68 USPQ2d 1424 (DC WNY 2003) and *University of Rochester v. G.D. Searle & Co. et al.* CAFC [(03-1304) 13 Feb 2004] for the proposition that the written description requirement of the present application is not met. Applicant disagrees with this proposition, and points out that the *University of Rochester* cases are not applicable. As characterized by the examiner, the *University of Rochester* case concerned a patent claiming compounds, but did not "name even one compound that assays would identify as suitable for practice of the invention, or provide information such that one skilled in the art could identify suitable compounds." However, the specification of the present application *does* provide a structure suitable for practice of the claimed invention: specifically, human ALK. Therefore, *University of Rochester* does not apply.

Thus, the rejection of claims 10-17 and 21-23 for lack of written description under 35 U.S.C. § 112, second paragraph, is moot or overcome and Applicant respectfully requests that it be withdrawn.

Remarks Regarding 35 U.S.C. § 102(b)

Claims 10, 11, 12 and 21 stand rejected under 35 U.S.C. §102 as being anticipated by Maeda *et al.* (30 April 1999). Applicant respectfully traverses this rejection. Maeda *et al.* generally describes a rat brain receptor-like protein-tyrosine phosphatase PTPξ/RPTPβ that binds

Midkine. Claim 10, from which claims 11, 12 and 21 depend, claims a recombinant polypeptide comprising one or more, but not all regions of a full-length human pleiotrophin receptor protein. The protein-tyrosine phosphatase PTPξ/RPTPβ of Maeda *et al.* does not anticipate recombinant polypeptides of the pleiotrophin binding site of the human pleiotrophin receptor protein.

Thus, the rejection of claims 10, 11, 12 and 21, under 35 U.S.C. § 102(b), is overcome or moot and Applicant respectfully requests that it be withdrawn.

Conclusion

The application is in condition for allowance and the prompt issuance of a Notice of Allowance is respectfully requested. If there are any fees due with the filing of this Response, including any additional fees for an extension of time, Applicant respectfully requests that extension and also requests that any and all fees due be charged to Deposit Account No. 03-1952 referencing Attorney Docket No. 54458-20002.00.

Respectfully submitted,
Morrison & Foerster LLP

Date: July 26, 2004

By _____
James Remenick
Registration No. 36,902

CUSTOMER NUNBER 25227
Morrison & Foerster LLP
1650 Tyson's Blvd., Suite 300
McLean, VA 22102
(703) 760-7700 (telephone)
(703) 760-7777 (telecopier)